

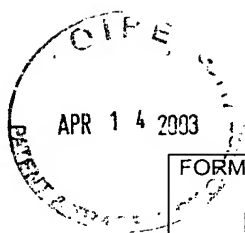
APR 14 2003

Sheet 1 of 9

FORM PTO-1449		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: CV01382K		SERIAL NO.: 10/057,629	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)				APPLICANT: Harry R. Davis			
				FILING DATE: January 25, 2002		GROUP: 1614	
U.S. PATENT DOCUMENTS							
*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE
	FQ	US2003/0013729	01/16/03	Iqbal, et al.	514		
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO
MS	FR	WO 96/19450	06/27/96	PCT	C07D	205/08	
	FS	WO 97/21676	06/19/97	PCT	C07D	205/09	
	FT	WO 97/41098	11/06/97	PCT	C07D	205/09	
	FU	WO 00/23415	04/27/00	PCT	C07C	69/734	
	FV	WO 00/23416	04/27/00	PCT	C07C	69/734	
	FW	WO 00/23425	04/27/00	PCT	C07D	209/80	
	FX	WO 00/23445	04/27/00	PCT	C07D	471/12	
	FY	WO 00/23451	04/27/00	PCT	C07D	487/14	
	FZ	WO 00/28981	05/25/00	PCT	A61K	31/00	
	GA	WO 00/31548	06/02/00	PCT	G01N	33/68	
	GB	WO 00/32189	06/08/00	PCT	A61K	31/415	
	GC	WO 00/34240	06/15/00	PCT	C07D	205/08	
	GD	WO 00/37057	06/29/00	PCT	A61K	9/48	
	GE	WO 00/37078	06/29/00	PCT <i>abstract only</i>	A61K	31/44	X(abs.)
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	GG	WO 00/38722	07/06/00	PCT	A61K	45/06	
	GH	WO 00/38723	07/06/00	PCT	A61K	45/06	
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	GX	WO 00/60107	10/12/00	PCT	C12P	17/10	
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HA	WO 00/63190	10/26/00	PCT	C07D	265/38		
HB	WO 00/63196	10/26/00	PCT	C07D	277/04		
HC	WO 00/63209	10/26/00	PCT	C07D	471/04		
MS	HD	WO 00/63703	10/26/00	PCT	C07D	33/92	

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FORM PTO-1449

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.:
CV01382KSERIAL NO.:
10/057,629INFORMATION DISCLOSURE STATEMENT
BY APPLICANTAPPLICANT:
Harry R. Davis

(Use several sheets if necessary)

FILING DATE:
January 25, 2002GROUP:
1614

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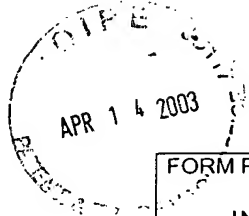
Sheet 3 of 9

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)				APPLICANT: Harry R. Davis			
				FILING DATE: January 25, 2002		GROUP: 1614	
<input checked="" type="checkbox"/>	IZ	WO 02/072104	09/19/02	PCT	A61K	31/54	
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<input checked="" type="checkbox"/>	JE	WO 03/018059	03/06/03	PCT	A61K	45/06	
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
<input checked="" type="checkbox"/>	JF	Vaccaro, W.D. et al., "Sugar-substituted 2-azetidinone cholesterol absorption inhibitors: enhanced potency by modification of the sugar" <i>Bioorganic & Medicinal Chemistry Ltrs.</i> , Oxford, G.B., 8:313-318 (1998)					
<input checked="" type="checkbox"/>	JG	Vaccaro, W.D. et al., "Carboxy-substituted 2-azetidinones as cholesterol absorption inhibitors", <i>Bioganic & Medicinal Chem. Ltrs. Oxford, G.B.</i> 8:319-322 (1998)					
<input checked="" type="checkbox"/>	JH	H. Davis et al., "Ezetimibe, a Potent Cholesterol Absorption Inhibitor, Inhibits the Development of Atherosclerosis in Apo E Knockout Mice", <i>Arterioscler, Thromb. Vasc. Biol</i> 21:2032-2038, (Dec. 2001)					
<input checked="" type="checkbox"/>	JI	Simova, E., "Aldol-type addition of hydrocinnamic acid esters to benzylideneaniline", <i>Chemical Abstracts No. 15</i> , 86 (April 11, 1997)					
<input checked="" type="checkbox"/>	JJ	Otto et al., "Stereochemistry of dehydration and halogenation of αR^* and αS^* isomeric 3-(α -hydroxybenzyl)-1,4 diphenyl-2 azetidinones, <i>Chemical Abstracts No. 19</i> , 99 (Nov. 7, 1983)					
<input checked="" type="checkbox"/>	JK	T. Durst et al., "Metallation of N-Substituted β -Lactams. A Method of the Introduction of 3-substituents into β -Lactams" <i>Canadian Journal of Chemistry</i> , 50:3196-3201 (1971)					
<input checked="" type="checkbox"/>	JL	Nobuki, O. et al., "Stereochemical syntheses of β -lactam derivatives by ultrasound promoted Reformatskii reaction" <i>Chemical Abstracts No. 106</i> , 17 (April 27, 1987)					
<input checked="" type="checkbox"/>	JM	M. Hoekman, et al., "Synthesis of Homologues of 4,5-Dihydroxy- and 4-Hydroxy-5-oxohexanoic Acid γ -Lactones", <i>J. Agric. Food Chem.</i> , 30:920-924 (1982)					
<input checked="" type="checkbox"/>	JN	H. Otto et al. "Darstellung und Stereochemie von 3-(α -Hydroxybenzyl)-1,4-diphenyl-2-azetidinonen", <i>Liebigs Ann. Chem.</i> 1152-1161 (1983)					
<input checked="" type="checkbox"/>	JO	G. George et al. "3-(1'-Hydroxyethyl)-2-Azetidinones From 3-Hydroxybutyrates and N-Arylaldimines" <i>Tetrahedron Letters</i> , 26:3903-3906 (1985)					
<input checked="" type="checkbox"/>	JP	Hart et al. "An Enantioselective Approach to Carbapenem Antibodies: Formal Synthesis of (+)-Thienamycin", 26 <i>Tetrahedron Letters</i> , 45:5493-5496 (1985)					
<input checked="" type="checkbox"/>	JQ	Panfil, I. et al. "Synthesis of β -Lactams from α , β -Unsaturated Sugar δ -Lactones" 24 <i>Heterocycles</i> 6:1609-1617 (1986)					
<input checked="" type="checkbox"/>	JR	D. Roger Illingworth, "An Overview of Lipid-Lower Drugs" <i>Drugs</i> 36:63-71 (1988)					
<input checked="" type="checkbox"/>	JS	Joseph L. Witztum, M.D., "Current Approaches to Drug Therapy for the Hypercholesterolemic Patient" <i>Circulation</i> 80:1101-1114 (1989)					
<input checked="" type="checkbox"/>	JT	B. Ram et al. "Potential Hypolipidemic agents: Part V", 29B Indian J. Chem. 1134-37 (1990)					
<input checked="" type="checkbox"/>	JU	Schnitzer-Polokoff, R. et al., "Effects of Acyl-CoA: Cholesterol O-Acyltransferase Inhibition on Cholesterol Absorption and Plasma Lipoprotein Composition in Hamsters" <i>Comp. Biochem. Physiol.</i> 99A:665-670 (1991)					
<input checked="" type="checkbox"/>	JV	Horie, M. et al, "Hypolipidemic effects of NB-598 in dogs" <i>Atherosclerosis</i> 88:183-192 (1991)					
<input checked="" type="checkbox"/>	JW	Baxter, A., "Squalestatin 1, a Potent Inhibitor of Squalene Synthase, Which Lowers Serum Cholesterol in Vivo", <i>The Journal of Biological Chemistry</i> 267:11705-11708 (1992)					
<input checked="" type="checkbox"/>	JX	Summary Factfile, "Anti-Atherosclerotic Agents" <i>Current Drugs Ltd.</i> (1992)					

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FORM PTO-1449		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO.: CV01382K	SERIAL NO.: 10/057,629
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)			APPLICANT: Harry R. Davis	
			FILING DATE: January 25, 2002	
			GROUP: 1614	
JY	JY	Harwood H. James, "Pharmacologic consequences of cholesterol absorption inhibition: alteration in cholesterol metabolism and reduction in plasma cholesterol concentration induced by the synthetic saponin β -tigogenin cellobioside (CP-88818; tiqueside) 1" <i>Journal of Lipid Research</i> 34 :377-395 (1993)		
	JZ	Salisbury, B. <i>et al.</i> , "Hypocholesterolemic activity of a novel inhibitor of cholesterol absorption, SCH 48461" <i>Atherosclerosis</i> 115 :45-63 (1995)		
	KA	Clader, J. W. <i>et al.</i> , "Substituted (1,2-Diarylethyl)amide Acyl-CoA;Cholesterol Acyltransferase Inhibitors: Effect of Polar Groups in Vitro and in Viro Activity" <i>Journal of Medicinal Chemistry</i> 38 :1600-1607 (1995)		
	KB	Sybertz, E., "Sch 48461, a novel inhibitor of cholesterol absorption" <i>Atherosclerosis</i> pp. 311-315 (1995)		
	KC	Vaccaro, W, <i>et al.</i> , "2-Azetidinone Cholesterol Absorption Inhibitors; Increased Potency by Substitution of the C-4 Phenyl Ring", <i>Bioorg. & Med. Chem.</i> 6 :1429-1437 (1998)		
	KD	G. Wu <i>et al.</i> , "A Novel One-Step Diastereo- and enantioselective formation of trans-azetidinones and its application to the total synthesis of cholesterol absorption inhibitors A.C.S. (4/21/99).		
	KE	B. Staels, "New Roles for PPARS in Cholesterol Homeostasis", <i>Trends in Pharmacological Sciences</i> , 22 :9 p. 444 (Sept. 2001)		
	KF	Abbott <i>et al.</i> , "Tricor® Capsules, Micronized", <i>Physicians Desk Reference</i> , January 8, 2001.		
	KG	M. Feher <i>et al.</i> , 1991, <i>Lipids and Lipid Disorders</i> , p.1-87 (1991).		
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	KI	C. Dujovne <i>et al.</i> , "Reduction of LDL Cholesterol in Patients with Primary Hypercholesterolemia by SCH 48461: Results of a multicenter Dose-Ranging Study", <i>J. Clin. Pharm.</i> 41 :1 70-78 (Jan. 2001)		
	KJ	W. Oppolzer <i>et al.</i> , "Asymmetric Diels - Alder Reactions, Facile Preparation and Structure of Sulfonamido - Isobornyl Acrylates", <i>Tetrahedron Letters</i> No. 51, 25 :5885-5888 (1984).		
	KK	M. Davidson <i>et al.</i> , "Colesevelam Hydrochloride: a non-absorbed, polymeric cholesterol lowering agent", <i>Expert Opinion Investigating Drugs</i> , 11 :2663-71, (Nov. 2000)		
	KL	M. Davidson <i>et al.</i> , "Colesevelam hydrochloride (cholestagel): a new, potent bileacid sequestrant associated with a low incidence of gastrointestinal effects", <i>159 Arch. Intern. Med.</i> 16 1893-900 (Sept. 1999)		
	KM	I. Wester, "Cholesterol - Lowering effect of plant sterols", <i>Euro. J.Lipid, Sci. Tech.</i> 37 -44 (2000).		
	KN	A. Andersson <i>et al.</i> , "Cholesterol -lowering effects of a stanol ester-containing low fat margarine used in conjunction with a strict lipid-lowering diet", <i>1 European Heart. J. Supplements</i> S80 - S90 (1999)		
	KO	H. Gylling <i>et al.</i> , "Reduction of Serum Cholesterol in Postmenopausal Women with Previous Myocardial Infarction and Cholesterol Malabsorption induced by Dietary Sitostanol Ester Margarine, <i>96 Circulation</i> 12 4226-4231 (Dec. 16, 1997)		
KP	T. Miettinen <i>et al.</i> , "Reduction of Serum Cholesterol with Sitostanol-Ester Margarine in a Mildly Hypercholesterolemic Population", <i>New England Journal of Med.</i> 333 1308-1312 (Nov. 16, 1995)			
KQ	T. Bocan <i>et al.</i> , "The ACAT Inhibitor Avasimibe Reduces Macrophages and Matrix Metalloproteinase Expression in Atherosclerotic Lesions of Hypercholesterolemic Rabbits", <i>Arterioscler Thromb Vasc. Biol.</i> 70 -79 (Jan. 2000)			
KR	M. Van Heek <i>et al.</i> , "In Vivo Metabolism - Based Discovery of a Novel Cholesterol Absorption Inhibitor, SCH 58235, in the Rat and Rhesus Monkey through the identification of the active metabolites of SCH48461," <i>283 J. Pharmaceutical and Experimental Therapeutics</i> 1 157-163 (1997)			

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Sheet 5 of 9

FORM PTO-1449		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO.: CV01382K	SERIAL NO.: 10/057,629
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)			APPLICANT: Harry R. Davis	
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MS	KS	H. Davis <i>et al.</i> , "The Cholesterol Absorption Inhibitor Ezetimibe Inhibits the Development of Atherosclerosis in apo E knockout (-/-) mice fed low fat and western diets," <i>151 Atherosclerosis</i> 1:133 (July 2000)		
	KT	L. Nguyen <i>et al.</i> , "Unexpected Failure of Bile Acid Malabsorption to Stimulate Cholesterol Synthesis in Sitosterolemia with Xanthomatosis", <i>10 Atherosclerosis</i> 2, 289-297 (1990)		
	KU	L. Nguyen <i>et al.</i> , "Regulation of Cholesterol Biosynthesis in Sitosterolemia: effects of lovastatin, Cholestyramine, and dietary sterol restriction," <i>32 J.Lipid Res.</i> 1941-1948 (1991)		
	KV	M. Cobb <i>et al.</i> , "Sitosterolemia: Opposing Effects of cholestyramine and Lovastatin on Plasma Sterol Levels in a Homozygous Girl and Her Heterozygous Father," <i>45 Metabolism</i> 6 673-679 (June 1996)		
	KW	M. Huettinger <i>et al.</i> , "Hypolipidemic Activity of HOE-402 is mediated by Stimulation of the LDL Receptor Pathway", <i>13 Arteriosclerosis and Thrombosis</i> 7 1005-1012 (July 1993).		
	KX	J. Best <i>et al.</i> , "Diabetic Dyslipidaemia", <i>59 Drugs</i> 5 1101-1111 (May 2000)		
	KY	P. Chong, <i>et al.</i> , "Current, New and Future Treatment in Dyslipidaemia and Atherosclerosis", <i>60 Drugs</i> 1 55-93 (July 2000)		
	KZ	M. Brown <i>et al.</i> , "A Receptor - Mediated Pathway for Cholesterol Homeostasis", <i>232 Science</i> 34-47 (April 4, 1986)		
	LA	L. Lipka <i>et al.</i> , "Reduction of LDL-Cholesterol and Elevation of HDL-Cholesterol in Subjects with Primary Hypercholesterolemia by SCH 58235: Pooled Analysis of Two Phase II Studies", <i>JACC</i> 257A (Feb. 2000)		
	LB	Medical Economics, Co., Inc., <i>Physician's Desk Reference</i> , 207-208, 2054 (55 th Ed. 2001)		
	LC	K. Fassbender <i>et al.</i> , "Simvastatin Strongly Reduces Levels of Alzheimer's Disease β -Amyloid Peptides $A\beta$ 42 and $A\beta$ 40 in vitro and in vivo", <i>PNAs Early Edition</i> , www.phas.org/cgi/doi/10.1073/phas.081620098 (2001)		
	LD	Andrx Announces Results of Alzheimer's Disease Clinical Study", <i>Andrx Corporate Release</i> (April 11, 2001)		
	LE	Andrx (ADRX): Pos Phase II Results Using Avicor in Alzheimer's: Str Buy; \$130", <i>US Bancorp Piper</i> , April 12, 2001		
	LF	Statins May Protect Against Alzheimer's Disease; much research needed", <i>Geriatrics</i> February 2001		
	LG	Dementia and Statins", <i>The Lancet</i> March 17, 2001		
	LH	Research & Development: Andrx Says Cholesterol Drug May Treat Alzheimers", <i>Reuters</i> April 11, 2001		
	LI	Cholesterol Drugs Ease Alzheimer's Damage; www.usatoday.com April 10, 2001		
	LJ	Lovastatin XL of Use in Alzheimer's? News Edge (May 2, 2001)		
	LK	L. Refolo <i>et al.</i> , "Hypercholesterolemia Accelerates the Alzheimer's Amyloid Pathology in a Transgenic Mouse Model, <i>Neurobiology of Disease</i> 321-331 (2000)		
	LL	D. Kang <i>et al.</i> , "Modulation of Amyloid β -protein Clearance and Alzheimer's Disease Susceptibility by the LDL Receptor - Related Protein Pathway", <i>Journal of Clinical Investigation</i> 106:9, 1159-1166 (Nov. 2000)		
	LM	Y.A. Kesaniemi, "Intestinal Cholesterol Absorption Efficiency in Man is Related to Apoprotein E Phenotype", <i>J. Clin. Invest.</i> 80(2) 578-81 (Aug. 1987)		
	LN	J. Busciglio <i>et al.</i> , "Generation of β -amyloid in the secretory pathway in neuronal and nonneuronal cells", <i>90 Proc. Nat'l. Acad. Sci, USA</i> , 2092-2096 <i>Neurobiology</i> (March 1993)		
	LO	L. Farrer <i>et al.</i> , "Assessment of Genetic Risk for Alzheimer's Disease Among first Degree Relatives", <i>Annals of Neurology</i> 25:5, 485-493 (May 1989)		
MS	LP	A. Goate <i>et al.</i> , "Segregation of a Missense Mutation in the Amyloid Precursor Protein Gene with Familial Alzheimer's Disease", <i>349 Nature</i> No. 6311704-1706 (Feb. 21, 1991)		

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Sheet 6 of 9

FORM PTO-1449		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: CV01382K	SERIAL NO.: 10/057,629
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MS	LQ	D. Mann <i>et al.</i> , "The Pattern of Acquisition of Plaques and Tangle in the Brains of Patients Under 50 years of Age with Down's Syndrome", 89 <i>J. Neuro. Sci.</i> , 169-179 (Feb. 1989)			
	LR	G. McKhann <i>et al.</i> , "Clinical Diagnosis of Alzheimer's Disease", 34 <i>Neurology</i> No. 7, 939-944 (July 1984)			
	LS	D. Selokoe, "Alzheimer's Disease: Genotypes, Pheontype and Treatments", 275 <i>Science</i> , 630-631 (Jan. 31, 1997)			
	LT	C. Van Duijn, <i>et al.</i> , "Familial Aggregation of Alzheimer's Disease and Related Disorders: A collaborative Re-Analysis of Case-Control Studies", 20 <i>Int'l J. Epidemiology</i> No. 2 (Suppl. 2), 513-520 (1991)			
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FORM PTO-1449		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: CV01382K	SERIAL NO.: 10/057,629
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				APPLICANT: Harry R. Davis	
(Use several sheets if necessary)				FILING DATE: January 25, 2002	GROUP: 1614
MN		Lutjohann <i>et al.</i> , "Sterol Absorption and Sterol Balance in Phytosterolemia Evaluated by Deuterium-Labeled Sterols: Effect of Sitostanol Treatment", <i>J. Lipid Res.</i> ; 36 :8; 1763-1773 (1995)			
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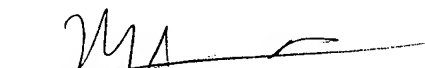
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)				APPLICANT: Harry R. Davis	
				FILING DATE: January 25, 2002	
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)				APPLICANT: Harry R. Davis	
				FILING DATE: January 25, 2002	
MS	OB	P.F. Belamarich <i>et al.</i> , "Response to Diet and Cholestyramine in a Patient with Sitosterolemia", <i>Pediatrics</i> , 977-981, (December 1990)			
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MS	OE	International Search Report dated December 18, 2002 corresponding to PCT Application No. PCT/US02/01195			
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